PURDUE UNIVERSITY | College of Engineering

Engineering Faculty Document
No.: 75-24
November 19, 2024

TO: The Engineering Faculty

FROM: The Faculty of the Agricultural and Biological Engineering Department

RE: Change to Existing Certificate

The Faculty of the Agricultural and Biological Engineering Department has approved the following changes to the **Biotechnology Quality and Regulatory Compliance (BQRC) certificate** from the College of Engineering. This action is now submitted to the Engineering Faculty with a recommendation for approval.

TITLE:

Biotechnology Quality and Regulatory Compliance (BQRC) certificate

DESCRIPTION:

The intent of the proposed Biotechnology Quality & Regulatory Compliance (BQRC) Graduate Certificate is to grow professional capabilities in the areas of quality and compliance, laws and practices, and regulatory affairs. This program will enhance the students' abilities to locate and interpret laws and regulations relevant to the pharmaceutical industry; and then, design, implement, and monitor "best practices" in the organization to assure compliance. The program provides a broad and thorough understanding of the drug development process: from early discovery and toxicology research, through clinical trials and manufacturing, and finally registration. Completion of this program allows graduates to see the "big picture" in their everyday work life, and better able to contribute in cross functional teams and across the organization's components.

RATIONALE:

The total number of credit hours for graduate certificate completion will change from twelve to nine credits (four courses to three). This allows students the ability to complete the certificate in one calendar year. In addition, we request that all three courses apply to the MS degree in the event that the student opts to continue in the MS BIRS concentration. The courses required will now only be: ABE 51100 Drug Development, ABE 51200 Good Regulatory Practices, and ABE 51300 Quality Management, Audits, Inspections, removing ABE 51500 – Molecular Basis in Manufacturing.

Head/Director of the Agricultural and Biological Engineering Department

Link to Curriculog entry:

https://purdue.curriculog.com/proposal:30697/form

Plan of Study for Certificate:

Required Core Courses ~~(12 cr)~~ (9 cr)

- ABE 51100 Drug Development (3 cr)
- ABE 51200 Good Regulatory Practices (3 cr)
- ABE 51300 Quality Management, Audits, and Inspections (3 cr)
- ~~ABE 51500 Molecular Basis in Manufacturing (3 cr)~~

Certificate can be obtained by graduate students or independent of a degree program (professional development)